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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,630	12/21/2001	Birgit Jung	I/1179	5076

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EXAMINER

BELYAVSKYI, MICHAIL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,630

Applicant(s)

JUNG ET AL.

Examiner

Michail A Belyavskyi

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 and 25-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-41 are pending.
 2. Applicant's election without traverse of Group XI, claims 23 and 24 in the reply filed on 07/06/2004 is acknowledged.
 3. Claims 1-22, 25-41 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.
- Claims 23 and 24 are under consideration in the instant application.*
4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*.
 5. Claim 23 objected to because of the following informalities: A word "method" is missing in the first sentence after the letter 'A'. Appropriate correction is required.
 6. The following is a quotation of the second paragraph of 35 U.S.C. 112.
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
 7. Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 8. Claim 23 is indefinite and ambiguous in the recitation of UDD protein in the second line. Recitation of a protein without providing SEQ ID NO for the protein is indefinite and ambiguous because different laboratories may have the same name for a different proteins .

In addition , Claim 23 being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is resolution step: it is unclear how to monitor or diagnose a chronic inflammatory airway disease after steps (a) – (c) are completed.

Art Unit: 1644

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for diagnosing or monitoring a chronic inflammatory airway disease, comprising determining the levels of UDD-protein consisting of an amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 8 does not reasonably provide enablement for a method for diagnosing or monitoring a chronic inflammatory airway disease, comprising determining the levels of any UDD-protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification discloses a results of differential gene expression analysis of healthy and patient with chronic inflammatory airway disease. The obtained data clearly indicated that expression of very specific UDD proteins of SEQ ID NOS: 4 and 8 were up-regulated in patient with chronic inflammatory airway disease (see Examples 2 and 3 in particular). The specification does not adequately teach a differential gene expression of any UDD-protein that can be used for monitoring or diagnosing chronic inflammatory airway disease. The specification does not teach how to extrapolate data of up-regulation of very specific UDD protein of SEQ ID NOS: 4 and 8 that can be used in a method for monitoring or diagnosing chronic inflammatory airway disease to develop a method for monitoring or diagnosing chronic inflammatory airway disease, comprising determining the level of any UDD-protein expression that commensurate in scope with the claimed invention. Moreover, the disclosed results clearly indicates that expression of very specific UDD proteins of SEQ ID NOS: 4 and 8 were up-regulated in patient with chronic inflammatory airway disease. Said results clearly teaches away from the claimed method for diagnosing or monitoring a chronic inflammatory airway disease, comprising determining the levels of any UDD-protein. Therefore, it is not clear that the skilled artisan could predict the efficacy of method for diagnosing or monitoring a chronic inflammatory airway disease, comprising determining the levels of any UDD-protein.

Art Unit: 1644

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed method for diagnosing or monitoring a chronic inflammatory airway disease, comprising determining the levels of *any* UDD-protein in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

10. Claims 38 and 43-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of : a method for diagnosing or monitoring a chronic inflammatory airway disease, comprising determining the levels of UDD-protein consisting of an amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 8.

Applicant is not in possession of : a method for diagnosing or monitoring a chronic inflammatory airway disease, comprising determining the levels of *any* UDD-protein

Applicant has disclosed only two species of UDD-protein consisting of an amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 8 that can be used in a method for diagnosing or monitoring a chronic inflammatory airway disease therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The sequences themselves are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

A description of a genus of protein sequences may be achieved by means of a recitation of a representative number of polypeptide sequences, defined by amino acid sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons

Art Unit: 1644

of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 “Written Description” Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.

12. Claims 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,307,035 as is evidenced by <http://users.rcn.com/jkimball.ma.ultranet/BiologyPages/I/Inflammation.html>, 2004.

US Patent ‘035 teaches a method for monitoring or diagnosis diseases associated with abnormal expression of UDD-protein (see entire document, Abstract and column 11 in particular).

US Patent ‘035 teaches UDD-protein of SEQ ID NO:18 that is 100 % identical to the claimed UDD-protein of SEQ ID NO: 4 (see attached sequence alignment). US Patent ‘035 teaches that abnormal expression of UDD-protein associated with various diseases, including lung cancer (see overlapping columns 11 and 12 in particular).

As is evidenced by <http://users.rcn.com/jkimball.ma.ultranet/BiologyPages/I/Inflammation.html>, 2004, chronic inflammatory airway diseases, including chronic bronchitis and COPD are frequent cause of lung cancer thus a method taught by US Patent ‘035 would inherently diagnose or monitor a chronic inflammatory airway disease.

Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02.

The reference teaching anticipates the claimed invention.

Art Unit: 1644

13. No claim is allowed.


14. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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August 23, 2004


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